K021922

JUN 2 5 2002

Special 510(k): Device Modification
Para® 5X – ~~K011410~~

Summary of Safety and Effectiveness

510(k) Submitter:	Streck Laboratories, Inc. 7002 South 109th Street La Vista, NE 68128	
Official Correspondent:	Carol Thompson Quality Assurance/Regulatory Affairs Manager (402) 537-5313	
Date Prepared:	June 5, 2002	
Names of Device:	Trade Name:	Para® 5X
	Common Name:	Assayed hematology control
	Classification Name:	Hematology Quality Control Mixture
Predicate Device:	STaK-Chex (K911582), manufactured by Streck Laboratories, Inc.	

Description: Para® 5X is a tri-level multi-parameter hematology control consisting of stabilized human red blood cells, human white blood cells and simulated platelets. The product is packaged in glass vials containing 3 ml. The closures are polypropylene screw caps with pierceable liners.

Intended Use: Para 5X is intended for use as a multi-parameter quality control material for ABX Pentra 60 C+ and Beckman Coulter™ AcT™ hematology analyzers. It includes assay values for CBC/Diff parameters.

Design Control Activities: Para 5X has not undergone a formulation or intended use change. Para 5X was evaluated on instrumentation for the ability to provide stable Baso information.

Testing Performed: Studies were conducted to establish performance of Para 5X Baso % and # addition; Open Vial Stability, Long-Term Stability (Shelf Life) and Alternate/Off-Site testing. All testing showed that Para 5X is consistently reproducible and performs within the claims.

Conclusions Drawn from the Tests: Para 5X is a safe and effective product useful for controlling the counting procedures of ABX Pentra 5X C+ and Beckman Coulter AcT hematology analyzers. It will perform as claimed when used in accordance with the package insert instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 5 2002

Mr. Paul Kittelson
Quality Assurance Coordinator
Streck Laboratories, Inc.
7002 South 109th Street
La Vista, Nebraska 68128

Re: k021922
Trade/Device Name: Para® 5X
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology QC Mixture
Regulatory Class: II
Product Code: JPK
Dated: June 5, 2002
Received: June 11, 2002

Dear Mr. Kittelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: _____

Device Name: PARA® 5X

Indications For Use: Para 5X is intended for use as a multi-parameter quality control material for ABX Pentra 60 C+ and Beckman Coulter™ AcT™ hematology analyzers. It includes assay values for CBC/Diff parameters.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Date: _____

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021922